IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INTEGRA LIFESCIENCES CORP., INTEGRA LIFESCIENCES SALES LLC, CONFLUENT SURGICAL, INC., AND INCEPT LLC, Plaintiffs, v. HYPERBRANCH MEDICAL TECHNOLOGY, INC., Defendant.	C.A. No. 15-819-LPS-CJB **PLAINTIFFS' EXHIBIT 1** **FILED UNDER SEAL**

JOINT LETTER TO THE HONORABLE CHRISTOPHER J. BURKE
ADDRESSING OUTSTANDING ISSUES
RELATING TO PLAINTIFFS' BIOCOMPATIBILITY THEORY

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Dear Judge Burke:

The parties submit this 3-page joint letter in compliance with the Court's Oral Order of December 14, 2017, ordering the parties to meet and confer "to address outstanding issues relating to Plaintiffs biocompatibility theory, including: (a) any further focused expert discovery that is required, or (b) any claim construction disputes that require Court resolution, and (c) how these processes may be incorporated into the existing case schedule." Having met and conferred and being unable to reach agreement on what further process is required, the parties submit their respective proposals.

Plaintiffs' Proposal. Plaintiffs' position is that all the issues can be addressed in a subsequent targeted round of expert reports and oral argument in conjunction with the currently scheduled January 5, 2018 oral argument on dispositive and *Daubert* motions. Plaintiff's position is simple. The prior art amino-PEG hydrogels relied on by Dr. Lowman would not have been looked to by one of skill alone or for modification because one of skill would understand those amino-PEG hydrogels to have caused "severe foreign body response," "severe inflammation," and "thick encapsulation of the hydrogel and abscess formation" according to Wallace '725. *See Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007) ("Significantly, the closest prior art compound . . . exhibited negative properties that would have directed one of ordinary skill in the art away from the compound . . . one of ordinary skill [instead] would have chosen one of the many compounds . . . that did not disclose the existence of toxicity or side effects.").

All claims and claim language at issue have already been addressed in the expert reports, depositions and summary judgment papers. Each side was under the same time constraints to prepare expert reports. HyperBranch knew full well the scheduling. HyperBranch has raised new invalidity positions based on the term "biocompatible" purportedly being invalid under 35 U.S.C. § 112. But, no further discovery is needed because issues of claim construction and Section 112 sufficiency are based on the intrinsic evidence which HyperBranch has had for years. HyperBranch's Final Invalidity Contentions allege that claim terms including the term "biocompatible" are invalid under Section 112, and they have assigned art to those claim terms in their final invalidity claim charts. So, those terms have already been construed by them and their experts based on the intrinsic evidence. There is no inconsistency in Plaintiff's position that one of skill would have understood the prior art amino-PEG hydrogels to lack biocompatibility based on Wallace while also maintaining that the claims satisfy Section 112 requirements based on the specification. The former is based on the prior art, while the latter is based on the specifications (and not the prior art). Plaintiffs assert that the issues are narrow and well-defined and already addressed in the expert reports, depositions and summary judgment papers. Plaintiffs disagree with HyperBranch's characterizations below. To address HyperBranch's new Section 112 invalidity theories with respect to the '034 and '5,705 patents, the plaintiffs suggest that Dr. Lowman's October 13, 2017 reply expert report be treated as an opening report on those issues and that Dr. Mays be permitted to respond only to those Section 112 issues raised in Dr. Lowman's October 13, 2017 reply report by submitting a sur-rebuttal report, a copy of which is attached hereto as Exhibit 1 and is being provided to Defendant today.

Plaintiffs further propose that Dr. Lowman be permitted to serve a sur-reply report in response to Dr. Mays' sur-rebuttal report, if deemed necessary, by January 2, 2018. As Dr. Lowman's October 13, 2017 report is being treated as the opening expert report on these Section

112 issues, i.e., "a complete statement of all opinions" and "the basis and reasons for them" that Dr. Lowman will express regarding these Section 112 issues including "… all facts or data considered by the witness in forming them," Dr. Lowman's "sur-reply" report should not introduce additional new matters, but be limited to responding to the specific matters raised in Dr. Mays' sur-rebuttal report (Exhibit 1).

Plaintiffs also propose that the parties may prepare slides for the January 5, 2018 oral argument summarizing their and their experts' positions on these matters. To the extent that there are deemed to be claim construction issues raised with respect to these Section 112 issues, Plaintiffs submit that those claim construction issues are addressed in the parties' respective summary judgment and *Daubert* motion papers, and that any questions the Court may have regarding possible claim construction issues can be adequately addressed at the hearing on those motions, currently scheduled for January 5, 2018.

HyperBranch's Proposal. Plaintiffs introduced their new "biocompatible" theory via Plaintiffs' rebuttal expert reports served on October 2, 2017. Plaintiffs admit that they didn't develop this theory until late September, well after the close of discovery and after opening expert reports. Any process adopted by the Court should provide HyperBranch with a full and fair opportunity to discover all of the details of Plaintiffs' new "biocompatibility" theory—including what language in each asserted claim allegedly gives rise to a heightened biocompatibility requirement and what Plaintiffs contend that requirement means—and to address the implications of this theory for non-infringement and invalidity issues.

As part of their new "biocompatibility" argument, Plaintiffs and their experts contend, without expressly defining "biocompatible," that every asserted claim includes language requiring that the claimed hydrogels be "biocompatible." This assertion, if accepted by the Court, would impact non-infringement and invalidity issues for each claim, because the scope of the asserted claims would suddenly be fundamentally different from the scope understood by the parties for the first two years of this case. Discovery was conducted, claim construction undertaken, and substantive theories were all pursued without any view—by either party—that there was a dispute about the scope of the claims on this new issue of "biocompatibility."

Although Plaintiffs contend there is a "biocompatibility" requirement in the claims, their experts have already admitted that they are applying the term in a manner that is transparently contrary to the intrinsic record. Indeed, Plaintiffs' experts have admitted that their new interpretation narrows the claims so substantially that prior art hydrogel compositions approved by regulatory agencies in Europe and the FDA in the United States would not read on the claims. As such, Plaintiffs experts' new interpretation of the claims, if adopted, would render the claims invalid for indefiniteness, lack of written description and enablement, and under other grounds HyperBranch would have pursued had Plaintiffs timely raised their present assertion that *none* of the prior art hydrogel compositions satisfy their subjective "biocompatible" standard.

Moreover, the mere incantation of "biocompatible" does not provide any meaningful guidance regarding Plaintiffs' new position regarding the scope of the claims. The term 'biocompatibility" is recognized to have "ambiguity" and there are various different subjectively assessed "definitions of biocompatibility." (*See, e.g.*, https://en.wikipedia.org/wiki/Biocompatibility.) In this regard, during the meet-and-confer, HyperBranch requested that Plaintiffs identify the

specific claim language they contend imposes the "biocompatibility" requirement and disclose the specific constructions they believe the Court should adopt under their new "biocompatibility" theory. Plaintiffs, however, would not agree to state what they contend to be the scope of the claims under their "biocompatibility" theory. Plaintiffs' refusal is telling; they simply want to leave the claims ambiguous and undefined. Thus, resolving the scope of the claims—i.e., whether the claims have claim language that imposes a heightened "biocompatibility" requirement and, if so, the proper construction of any such claim language—is a necessary step in properly addressing Plaintiffs' newly introduced "biocompatibility" theory.

To allow the Court to resolve the questions of claim construction posed by Plaintiffs' new "biocompatibility" theory on a complete record and to allow HyperBranch the appropriate due process to respond accordingly, HyperBranch proposes: (1) HyperBranch to serve targeted written discovery on Plaintiffs relevant to the new "biocompatibility" theory (see Ex. A-B, attached hereto); (2) the Court resolve the parties' pending claim construction dispute regarding whether there is any heightened "biocompatibility" requirement in the claims as asserted by Plaintiffs; (3) if the Court finds that the claims impose a heightened "biocompatibility" requirement, supplemental claim construction briefing to construe the relevant claim limitations; and (4) supplemental expert discovery under the newly asserted claim scope. HyperBranch believes that these events can be addressed under the following schedule:

Schedule	**Date**
Plaintiffs' responses to supplemental written discovery (Exs. A-B)	January 3, 2018
Plaintiffs' opening supplemental expert reports	January 17, 2018
Defendant's rebuttal supplemental expert reports	January 31, 2018
A requested ruling from the Court on the limited question of whether the preambles of the claims are or are not limiting[1]	January 26, 2018 (requested)
Opening 10-page supplemental briefs if necessary[1]	February 7, 2018
Rebuttal 5-page supplemental briefs if necessary[1]	February 14, 2018

Finally, Plaintiffs' proposal that Dr. Lowman's reply report be treated as an opening report on Section 112 issues raised by Plaintiffs' new "biocompatibility" theory, and that HyperBranch and Dr. Lowman be precluded from raising any additional issues, is fundamentally unfair. As HyperBranch explained in its letter briefing on this issue, when Plaintiffs disclosed their new theory for the first time through expert rebuttal reports, Dr. Lowman was on a two-week trip to China, and he had a mere eleven days to consider Plaintiffs' new theories. He therefore was able to develop only preliminary opinions on Section 112 issues. HyperBranch and its experts should be afforded a full and fair opportunity to develop non-infringement and invalidity positions in light of Plaintiffs' new "biocompatibility" theory and any claim constructions the Court may adopt in response to that new theory.

[1] The parties' current summary judgment briefs address whether the preambles from claim 10 of the '034 patent and the claims of the '5,705 patent are limiting. If the preamble is not limiting, further claim construction on those claims would not be necessary.

Respectfully submitted,

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